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Speaking Up About FDA Regulations

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by Richard C. Thompson

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Americans tend to be outspoken and opinionated, and when something is happening that they think affects them, they are likely to speak up.

The Food and Drug Administration knows this more than most because FDA—which regulates food, drugs, cosmetics and other products—is probably closer to American daily life than any other federal agency.

Because FDA's actions can have great effect on the public health, on the industries it regulates, and even on the nation's economy, the agency conducts its rule-making in public so that all interested parties can be heard. It deliberately makes the public a part of the process.

When FDA intends to issue a new regulation or change one that already exists, it will—like any federal agency—announce that fact as a "notice of proposed rulemaking" in the *Federal Register*, the federal government's publication of record.

The *Federal Register* is published each weekday by the Government Printing Office and carries announcements of actions proposed and taken by the federal agencies. It is available by mail subscription and can also be found in many libraries, government offices, and congressional district offices.

The rule-making notice will give the text of the proposed regulation, describe the issues involved, and invite public comment. It will also explain in a preamble why FDA is proposing the regulation. Anyone wanting to comment will then know the reasoning behind the proposal and its legal and scientific background.

Besides telling what FDA intends, the notice will announce the "comment period." This is the deadline—usually several months away—for getting comments to the agency so that they can be considered and perhaps affect the decision. The notice will also give the name of the FDA staff member working on the proposal who can provide more information.

There are no forms to be filled out in order to submit a comment, and the comments need not follow any particular style. Some have arrived handwritten, some typed; on stationery, post cards and scribbled notes. But however they are submitted, the comment should say whether the writer is for or against the proposal, and why.

Comments should be mailed to the FDA Dockets Management Branch, Room 462, 5600 Fishers Lane, Rockville, Md. 20857.

FDA also welcomes comments and questions not related to any particular proposal. They should be addressed to the Consumer Inquiries Staff, Room 1686, 5600 Fishers Lane, Rockville, Md. 20857, or to FDA offices around the country (check the government listings in local telephone directories).

Comments are logged as they are received, then placed in the file for the proposal to which they refer. They are available with all other comments on that proposal to anyone who asks to see them in the agency's public reading room.

FDA staff will evaluate the comments in the course of reaching a decision and, when the decision is published in the *Federal Register*, will tell the effect the comments had on that decision.

Persons wanting to react to an FDA proposal do not have to have a title or official position. All that is needed is an informed opinion and the willingness to express it. In fact, persons making comments do not have to be citizens of the United States if what FDA is proposing concerns them.

One classic example of individual action affecting an FDA decision was the repeated efforts by a New Jersey pharmacist to get camphorated oil off the market as a dangerous and unnecessary product. (See "What Ever Happened To Camphorated Oil?" in *FDA Consumer*, July-August 1983.) The pharmacist first made his point to an FDA panel in 1978; then, over a two-year period, he submitted cases, comments and documentation that showed camphorated oil—sold for years as a liniment—had no medical uses and had caused many deaths and much illness when it was mistakenly ingested, most often by children. Based on his persistence and presentations, FDA ruled that camphorated oil could no longer be marketed and credited him with leading the agency to this decision.

In the first two months of 1985, the docket staff logged 1,968 comments on proposed rules that FDA had published. Of those, 615 came from individual consumers, 40 from commercial organizations, 32 from professional groups, and six from consumer organizations. Just over 800 were from other interests, such as universities, state and local governments, the news media, and organized constituencies sending form letters.

The subject of these comments covered a broad range of topics, such as setting new standards for bottled water, requiring a warning label on an acne drug, preserving various foods with irradiation, and changing a drug from prescription to nonprescription. A consumer group asked for the acne drug warning because it believed the medication should not be given to pregnant women for fear of birth defects, and they want the label to say so. New standards for bottled water would affect an entire industry, and the industry's comments reflect its concerns. The large number of comments on food irradiation show how strongly both the public and the food companies feel—both pro and con—about this subject and how they want FDA to be guided by their opinions.

Many persons believe that comments by business, industry and organized consumer groups count most with FDA. They are mistaken: To FDA, a comment is a comment and is judged on its legal and scientific merits, regardless of the source. However, the total volume of public comments can be a factor, as happened with the agency's proposal to ban saccharin in 1978. The thousands of comments opposing the ban showed how strongly people felt about keeping that artificial sweetener.

But one advantage that consumer groups and industry have over individuals is that they know what FDA is doing. They follow the subjects that interest them very closely. They understand the government's comment and petition system and how to make it work for them. Also, their presentations are often fully developed and can go on for several pages with scientific data and charts. But however well prepared, an industry comment for a proposal can be offset by another against it, or by comments from, say, a consumer group taking yet another position.

It's not enough for the comment to be for or against a proposal; it should also say why. FDA regulatory decisions are primarily based on science, and agency reviewers look for reasoning and logic and good science in the comments that come to them. Especially helpful are any new data not considered in the proposal.

While the notice-and-comment process is the way to make

Comments received on food irradiation

Individual consumers	*4,146*
Consumer organizations	*41*
Commercial organizations	*190*
Professional organizations	*48*
Universities, government agencies, news media, etc.	*332*
Form letters	*4,779*
Total	*9,536*

Using irradiation to preserve food has been a controversial issue for several years. (See "Irradiation Proposed To Treat Food" in the May 1984 FDA Consumer.) As of June 1985, almost 10,000 comments had been logged by the dockets staff since FDA proposed in 1981 to permit food irradiation, making it one of the most attention-getting proposals in FDA's history. The letter at top, from the Hawaii Department of Agriculture, urges irradiation for fruit exports; the letter below it wants irradiated foods to say so on the label; the form letter at bottom—one of hundreds received—was headed "Yes, We'll Take a Risk But We Want a Label!" Professional organizations shown in the chart include physician and scientist groups.

Dear Dr. Young:

The Food and Drug Administration has had under review for a considerable length of time a proposed regulation to expand the use of ionizing radiation as a food preservation and disinfestation process. Because an alternative treatment method is desperately needed by our papaya industry, we are writing to urge expeditious action by FDA on this long-pending review.

Following the Environmental Protection Agency's ban on the use of ethylene dibromide as a fumigant on September 1, 1984, Hawaii's papaya industry has been forced to utilize a double-dip hot water process to insure disinfestation of fruit destined for export. Although the process meets the quarantine requirements of the U.S. Department of Agriculture, it has numerous drawbacks which affect the quality and marketability of the fruit. This hot water treatment has greatly reduced the quantity of fruit being shipped to the mainland U.S. with consequent loss of markets.

Fortunately, there are several firms in our State capable of building and operating irradiators for the treatment of papayas and other products. Irradiation, of course, would open the Mainland markets for our other fruits such as lychee, mango and avocado.

Dear Dr. Young,
I am writing to express my strong support for Irradiation Labeling if indeed our food is to become irradiated. The enormous factors and results in such a process make it imperative to give the consumer a Choice in what food is purchased.

I understand the new regulation would open the door for food processors to use irradiation of, or together with, highly toxic chemical pesticides and fumigants to destroy insects and extend the shelf life of fresh fruits and vegetables.

I also understand that irradiation of a food at the proposed levels does not make food radioactive. This, however, is NOT the basis of my safety concerns. I am concerned with other radiolytic changes that DO occur.

I do NOT agree with FDA's conclusion that simply because the food does not become radioactive it is therefore "safe" and has the identical nutritional value as similar foods which have not been irradiated.

Instead I share the concern expressed by Dr. Samuel S. Epstein and John W. Gofman that "While not radioactive, irradiated food contains stable radiolytic products whose chemical identity and toxicology are poorly defined." (The Washington Post, February 25, p. A-16)

These new formed radiolytic products may or may not be highly toxic. At this time we simply don't know.

Dr. Epstein and Gofman pointed out that FDA's assurance they are safe does not come from critical, long term feeding tests of concentrated extracts of these radiolytic products for mutagenic, carcinogenic and other chronic toxic effects.

FDA states in its proposal that "Ionizing radiation, like other forms of energy used to process food, causes chemical changes in food."

At the dosage proposed by FDA irradiation of food "would produce approximately 30 parts per million of radiolytic products." Three parts per million or 10% of these may be entirely new substances that have never been tested for safety by *any agency of any government*. Thirty or three parts per million is an extremely high amount of very toxic poisons.

Drs. Epstein and Gofman said "Industry claims for the safety of irradiated food largely depend on insensitive conventional animal feeding tests, rather than the more critical long term feeding tests of concentrated extracts for carcinogenic and other chronic toxic effects." FDA should extend the comment time for nine months or more until at least one long-term feeding test of concentrated extracts of these newly discovered radiolytic products has been completed.

The Language Of Regulation

Code of Federal Regulations (CFR): A compilation of the current regulations of all federal agencies, revised and published once a year and kept up to date by the *Federal Register.* FDA's regulations are in Title 21 of the 50 titles that make up the CFR.

Federal Register (FR): The five-day-a-week government publication in which new, changed or proposed regulations of the federal agencies, as well as certain other government information and directives, are announced. Appearance of a document in the *Federal Register* gives an action or announcement legal standing and makes it official.

Copies of the *CFR* and *FR* are available in many libraries, courthouses and federal office buildings. They can also be purchased from the Superintendent of Documents, Government Printing Office (GPO), Washington, D.C. 20402. Write to GPO for prices.

Regulations: Detailed statements that describe exactly how the agency interprets and will apply the general legal authority it has been given through laws passed by Congress. FDA's basic authority comes from the Food, Drug, and Cosmetic Act; the Fair Packaging and Labeling Act; the Radiation Control for Health and Safety Act; and the Public Health Service Act. FDA enforces these laws in regulating food, drugs, cosmetics, medical devices, radiation-emitting products, and animal feed.

Advance Notices of Proposed Rulemaking (or Notices of Intent): Announcements intended to publicize an action the agency is considering. Such notices frequently precede issuance of a proposed regulation, and response to the notice can affect the form and substance of the proposal.

Proposed Regulations: Statements in the *Federal Register* that declare an agency's intention to revise existing or to issue new regulations. These proposals invite public comment as described in the accompanying article.

Petition: A formal request by an individual, firm or organization to the FDA commissioner that a certain action be taken or not be taken, or that a regulation or order be established, revoked or revised. ■

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opinions known to FDA on proposals the agency has already issued, there is also a petition process to urge FDA to initiate—or refrain from—a particular action.

Petitions are a formal request that FDA issue, amend or revoke a regulation. Unlike comments, petitions require considerable preparation.

The petitioner must cite appropriate statutes and regulations; submit a statement of the factual and legal basis for the petition, even including data unfavorable to the petition; and discuss any economic and environmental impact the requested action might have. Petitions should be filed with the Dockets Management Branch, and DMB staff can explain the requirements.

Unlike comments, a petition sets regulatory machinery in motion and involves considerable time, money and effort on the part of FDA. The process is there to be used, but it should not be used lightly.

The formality of a petition may discourage individuals, but it does not discourage business, industry and consumer organizations. There may be some 100 petitions in the agency awaiting resolution, not necessarily urgent and certainly not to be decided without proper study.

Most of these petitions are from commercial firms and deal with very specific and technical situations. They ask, for example, that nutrient listings in animal feed be revised; that permitted weights for margarine products be changed; that charcoal tablets be exempt from drug warnings; that labeling be changed on various food and drug products. Some ask, in effect, that the petitioner's product be excused from some provision of a regulation or that a competitor's be more closely regulated.

Petitioners often hope to obtain an economic advantage or to protect one that already exists. This happened when a new nonprescription analgesic was introduced, and a firm that had long dominated the market petitioned FDA to take action that would have restricted the newcomer's ability to advertise. The purpose was so obvious and so criticized that the petitioner asked to withdraw the request.

There have been petitions from professional organizations—such as physician groups who do not want prescription drugs to be advertised directly to consumers, and from pharmacists who believe a new medication should be dispensed only by them. Others are from consumer groups, asking that certain products, which they believe are unsafe or ineffective, be taken off the market. Only a few petitions are from individuals.

Petitions must be directed to the FDA commissioner and ultimately must be decided by him. The merits of the petition will first be weighed by agency staff and this can take several months or, if sufficiently complicated, more than a year. Then—knowing the pros and cons of the requested action—the commissioner will either grant or deny the petition, announcing the decision in the *Federal Register* as well as directly notifying the petitioner. If the result is not satisfactory, the petitioner may take the matter to court.

In addition to using comments and petitions to reach FDA, the agency schedules public meetings to discuss and explain its actions and proposals. Meetings with consumer groups and industry representatives—but open to anyone—are held in Washington, D.C. Others are held across the country, especially if the issues are highly controversial or will affect a great number of people. The meetings are announced in the *Federal Register* and through the news media.

Consumer groups, businesses and industry know how to affect FDA's decision-making process. They do it every day with comments and petitions. But average citizens with an opinion on an FDA action or proposal may be intimidated at the thought of approaching a federal agency. They need not be. For those who have a well-thought-out position on an issue affecting the public health in which FDA has a role, the process is well worth the effort. ■

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